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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/748,524
Filing Date: December 29, 2003
Appellant(s): PARIZEK ET AL.

Richard E. Parizek et al
For Appellant

EXAMINER'S ANSWER

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 94/22476	ROBERTS	10-1994
3,920,811	LUND	5-1975

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts (WO 94/22476, published October 13, 1994) in view of Lund (3,920,811 published November 18, 1975).

Claim 46 is drawn to a method of immunizing cattle without significant injection site lesion formation comprising injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six clostridial organisms, a protective antigen component from at least one non-clostridial organism which is *Moraxella bovis* (*M. bovis*), and an

encapsulating polymer adjuvant, whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished.

Claim 47 is drawn to a method of immunizing cattle without significant injection site lesion formation comprising injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from seven clostridial organisms, a protective antigen component from at least one non-clostridial organism which is *M. bovis,* and an encapsulating polymer adjuvant, whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished.

Claim 48 is drawn to a method of immunizing without significant injection site lesion formation comprising injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component *Cl. chauvoei, Cl. septicum, Cl novyi, Cl. perfringens type Cl, CL perfringens type D, CL. sordellii Cl. tetani* and *Cl. haemolyticum*, the protective antigen component from at least one non-clostridial organism which is *M. bovis,* and an encapsulating polymer adjuvant, whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is

reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished.

Roberts teaches methods of preventing or treating a clostridial infection in a bovine animal comprising administering a multicomponent clostridial vaccine comprising *Clostridium chauvoei*, *Clostridium septicum, Clostridium novyi, Clostridium sordellii, Clostridium perfringens,* Type C and Type D and *Clostridium haemolyticum,* and an adjuvant along (page 2-3, lines 25-10). Roberts teaches that non-clostridial antigens such as *Moraxella bovis,* are added to the multicomponent vaccines in order to afford protection against a wide spectrum of diseases (page 5, lines 10-15). Roberts teaches an embodiment directed to a multicomponent clostridial vaccine comprising two or more clostridial immunogens and a dispersible soluble adjuvant (page 2, lines 25-27). Roberts teaches immunizing cattle or bovine, by injecting between 1 to 5ml wherein the injection amount is as low as 0.5ml (page 8 lines 24-34).

Roberts teaches the bacterins and toxoids are administered in vaccine compositions including readily dispersible soluble adjuvants thereby avoiding chronic irritation at the injection site (page 6, lines 13-15). Roberts teaches that the rapidly dispersed, soluble adjuvants to exhibit low tissue reactivity should be used (page 4, lines 26-28). Roberts teaches that the vaccines are administered without harmful side effects and chronic inflammatory responses that produce granulomas and abscesses (page 4, lines30-33). Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability (page 1, lines 32-35). Roberts discloses the prior art as teaching other potent adjuvants, including CARBOPOL ^{TM} polymers have

been used with clostridial vaccines (page 2, lines 1-5). However Roberts does not specifically recite an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Lund teaches an adjuvant polymer, such as CARBOPOL ™, is retained at the site for prolonged slow release that acts by adsorbing the active agent onto the polymer (col.1-2, lines 67-5). Lund teaches readily mixable and easily dispensed adjuvants that stimulate the production of antibodies by the recipient (col. 2, lines 50-68). Lund teaches the inclusion of active agents such as *Clostridium perfringens* Types B, C and D, *Clostridium tetani, Clostridium chauvoei*, *Clostridium septicum, Clostridium haemolyticum, Clostridium novyi,* and *Clostridium sordellii* whose effects are prolonged or enhanced by their inclusion with the adjuvant polymers (col.5, lines 24-38). Examples 17-19 teach injecting CARBOPOL ™ and *Clostridial* bacterins without significantly lowering the potency of the *Clostridium* bacterins. Lund teaches the necessity and desirability of *Clostridium* vaccines to have adjuvants in order to pass potency test requirements and to take advantage of the good adjuvant properties of CARBOPOL ™ without significantly lowering the potency of the bacterin (col. 10-11, lines 63-9).

It is noted that the instant specification teaches that adjuvants polymers, function by encapsulating antigens and releasing them slowly (page 15, lines 13-18). The adjuvants are polymers, including block copolymers wherein a specific example of the preferred adjuvant is CARBOPOL ™ (page 15, lines 23-28). Therefore, the CARBOPOL

™ is an encapsulating polymer adjuvant that releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Therefore it would have been prima facie obvious at the time of Appellants" invention to apply the encapsulating polymer adjuvant of Lund's to Roberts method of immunizing cattle without significant injection site lesion formation comprising injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from at least six clostridial organisms, a protective antigen component from *M. bovis* and an encapsulating polymer adjuvant, whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished, in order to avoid irritation and significant lesion formation at the injection site. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the readily dispersible soluble adjuvants of Roberts for the adjuvant polymer of Lund because Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability of the bacterins and that clostridial vaccines are already known in the art to include CARBOPOL ™ polymers. Furthermore, no more than routine skill would have been required to exchange the adjuvant of Roberts for the commercially available and functionally equivalent encapsulating polymer adjuvant of Lund since Lund teaches that adjuvant polymers are retained at the injection site for prolonged slow release of antigens. Finally it would have been prima facie obvious to combine the invention of

Roberts and Lund to advantageously achieve low tissue reactivity within the cattle and avoid chronic inflammatory responses, granulomas and abscesses.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method of immunizing cattle without significant injection site lesion formation comprising amount of injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six or seven clostridial organisms, a protective antigen component from *M. bovis* and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished.

Appellant did not point to support in the specification for an injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished. Appellant has pointed to pages 54 and Tables 12 and 13 of the instant specification and claims for support of the amendment. However the reduction of lesions after weaning is only 33.2% not at least 41% in Table 12. Table 14 shows the quantity of trim in grams from a 5.0ml injection caused a 69.4g lesion and the 2.0ml injection caused a 30.3g lesion. Thus, there appears to be no teaching of an injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished. Therefore, it appears that the entire specification appears to fail to recite support for the method of immunizing cattle without significant injection site lesion formation comprising amount of injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six or seven clostridial organisms, a protective antigen component from at least one non-clostridial organism which is *M. bovis* and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished. Thus, it appears that there is no support in the specification. Therefore, the claims incorporate new matter and are accordingly rejected.

(10) Response to Argument

Response to Arguments Traversing the Rejection of Claims 46-48 Under

35 U.S.C. 103(a)

Appellants' assert that Roberts teaches against using polymeric adjuvants because Roberts specifically teaches that multicomponent clostridial vaccines should be made up using readily dispersible, water-soluble adjuvants rather than depot adjuvants, including CARBOPOL™, because those adjuvants "...usually provoke severe persistent local reactions, such as granulomas, abscesses and scarring..." which are reported to be "responsible for carcass blemish which requires expensive trimming, a consideration when the vaccine has been injected into muscle tissue destined to be a valuable cut of meat." (Page 2, lines 24-33).

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas*

Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Therefore Appellants" argument is not persuasive especially when considering other adjuvants such as CARBOPOL ™ have been used in clostridial vaccines.

Appellants' urge that the Examiner improperly combines the teaching found in Roberts with Lund, and submit that no *prima facia* case of obviousness has been made.

In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been prima facie obvious at the time of Appellants" invention to apply the encapsulating polymer adjuvant of Lund's to Roberts method of immunizing cattle without significant injection site lesion formation comprising injecting about 2ml of a multicomponent vaccine comprising a combination of *M. bovis*, components from at least six clostridial organisms, and an encapsulating polymer adjuvant, in order to avoid irritation and significant lesion formation at the injection site and stimulate antibody production by the

subject as taught by Roberts and Lund. Contrary to Appellants' statements, obviousness is established by combining or modifying the teachings of the prior art to produce the claimed invention where some teaching, suggestion, or motivation to do so is found either in the references because readily dispersible soluble adjuvants of Roberts for the adjuvant polymer of Lund because Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability of the bacterins and that clostridial vaccines are already known in the art to include CARBOPOL ™ polymers and this knowledge was generally available to one of ordinary skill in the art.

Appellants' argue that "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them [to achieve a desired result] is more likely to be nonobvious." KSR International v. Teleflex Inc. et al., 127 S.Ct. 1727 at 1740 (2007); United States v. Adams, 383 U.S. 39 at 51-52, 86 S.Ct. 708 (1966).

Despite Appellants' arguments, the Roberts reference does not teach away from the adjuvant. Moreover, all the claimed elements of administering to cattle a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from at least six clostridial organisms, *M. bovis,* a protective antigen component from at least one non-clostridial organism and an encapsulating polymer adjuvant, were known in the prior art as evidenced by Roberts and Lund. One skilled in the art could have combined the elements as claimed by

known methods as disclosed by both Roberts and Lund, with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, The Supreme Court in KSR noted that if the actual application of the technique would not have been beyond the skill of one of ordinary skill in the art, then the resulting invention would have been obvious because one of ordinary skill could have been expected to achieve it.

Appellants' assert that one of ordinary skill in the art reading Roberts would never find reason to combine it with Lund as Roberts teaches against using the depot adjuvants of Lund. "A reference may be said to be teaching away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Appellant." Ormco Corporation v. Align Technology, Inc., 463 F.3d 1299 at 1308, C.A. Fed. (Cal.), 2006; In re Kale, 441 F.3d at 990 (Fed.Cir. 2006).

It is noted that teaching away is different that teaching a different, equivalent alternative, which achieves that same purpose of being an adjuvant in a method of immunization with a clostridial multicomponent vaccine. Thus, solving the same problem with a functionally equivalent alternative is not a teaching away, as Appellants" urge. Furthermore, it is the Office's position that preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132

(Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that Appellant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.

In this case, the Roberts reference teaches multicomponent clostridial vaccines comprising the saponin adjuvant instead of the well known and previously used CARBOPOL. The Roberts reference, however, disclosed that CARBOPOL was known for this use, but is inferior to saponin. The Lund reference, like Roberts, teaches multicomponent clostridial vaccines using CARBOPOL™, because CARBOPOL is retained at the site for prolonged slow release that acts by adsorbing the active agent onto the polymer. Therefore, it is the Office position that the rejection be maintained, concluding that Appellant's argument that the reference teaches away from using CARBOPOL™, is insufficient to overcome the rejection since Appellants' asserted no discovery beyond what was already known in the art. Therefore contrary to Appellants'' argument, the prior art does not teach away from the instant claims.

Appellants' urge that Roberts clearly teaches against using an encapsulating polymer adjuvant that releases antigens slowly at the site of injection.

However, Roberts teaches administration of compositions using readily dispersible soluble adjuvants (page 4, lines 26-28 and page 6, lines 13-15). The CARBOPOL ™ polymer adjuvant is a readily dispersible soluble adjuvant. Thus a teaching of a different equivalent alternative, which achieves that same purpose of being an adjuvant in a method of immunization with a clostridial multicomponent vaccine is not a teaching away. Polymer adjuvants, including CARBOPOL ™, are known to readily absorb water and due to its hydrophilic nature, and the cross-linked structure are known to useable for controlled release drug delivery systems. Roberts even cites prior art references teaching the adjuvants can be admixed in liposomes, thus Roberts does not teach away from using an encapsulating polymer adjuvant that releases antigens slowly at the site of injection as Appellants' suggest.

Appellants'' assert that the ordinary practitioner would never, based on the teaching of Roberts, exchange the adjuvant of Roberts for an equivalent encapsulating polymer, as taught by Lund, as Roberts clearly teaches that such polymer adjuvants result in deleterious injection site lesion formation. Appellants' argue that Roberts does not suggest in any way that these problems could be overcome with low dose encapsulating polymer formulations.

However, Roberts may be relied upon because it reasonably suggest to one having ordinary skill in the art the administration of multicomponent vaccines in low dose volumes of about 2ml having dispersible, soluble adjuvants. Roberts states that

potent adjuvants such as CARBOPOL ™ have been used in clostridial vaccines. Therefore, Roberts have disclosed the polymer adjuvant even though Roberts refers to polymer adjuvants as nonpreferred embodiments. Roberts teaches: compositions using water dispersible, water soluble adjuvants; the previous use of CARBOPOL ™ with clostridial vaccines; and the use of polymer adjuvants such as liposomes. Lund teaches an adjuvant polymers, such as CARBOPOL ™, are retained at the site for prolonged slow release that acts by adsorbing the active agent onto the polymer. Finally, Roberts and Lund teach the instant claims, because the 2ml of the vaccine will result in a smaller lesion as compared with a 5ml injection of that same vaccine.

Appellants' assert that the differences between the prior art and the claims include Roberts' teaching that soluble adjuvants are required to reduce injection site lesion formation contrasted with Appellants".

Roberts teaches compositions using water dispersible, water soluble adjuvants without the harmful side effects and inflammatory responses; CARBOPOL ™ is an dispersible water soluble adjuvant that does not have inflammatory responses when administered in the 2ml dose and not the larger doses. This is further evidenced by Table 14 of Appellants' specification disclose that when comparing 2ml doses and 5ml does of the same vaccine, the incidence of lesions was significantly reduced. Thus, one can only concluded that the reduction of lesion is from the use of a smaller dose, rather then the use of different adjuvants.

Appellants' state that the primary reference teaches against using encapsulating polymer adjuvants and the secondary reference, in addition to being inconsistent with the primary reference, does not address the issue of injection site lesions and does not suggest using tow dose immunization methods.

In this case, it would have been prima facie obvious at the time of Appellants'' invention to apply the encapsulating polymer adjuvant of Lund's to Roberts method of immunizing cattle in order to avoid irritation and significant lesion formation at the injection site. Roberts clearly states that the low dose vaccines including rapidly dispersed, soluble adjuvants are administered without the harmful side effects and chronic inflammatory responses due to granulomas and abscesses (page 4, lines 25-33). Roberts teach administration of vaccines having emulsifying agents and aqueous suspensions (page 7, lines 1-9). Lund also teaches the administration of low dose clostridial vaccines in amounts 0.5 and 0.2ml doses (Examples 17 and 19). Therefore there is no inconsistency in the teachings of Roberts and Lund, contrary to Appellants' statements.

Appellants'' respectfully submit that the prior art references have been improperly combined as they reveal to the skilled practitioner two opposing teachings for selecting adjuvants.

Contrary to Appellants' statements, a practitioner of ordinary skill in the art would have a reasonable expectation of success by exchanging the readily dispersible soluble adjuvants of Roberts for the adjuvant polymer of Lund because Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability

of the bacterins and that clostridial vaccines are known to include CARBOPOL ™ polymers.

Appellants' state that if it can be concluded that Roberts teaches vaccine administration in 2ml dosages, which Appellants' do not concede, the dosages taught apply only to vaccines based on soluble adjuvants and not vaccines comprising depot adjuvants, such as Appellants" encapsulating polymer adjuvants.

However, Roberts teaches immunizing cattle or bovine, by injecting between 1 to 5ml wherein the injection amount is as low as 0.5ml (page 8 lines 24-34); therefore Roberts clearly teach administration of 2ml doses. It is agreed that Roberts teaches vaccines based on soluble adjuvants, and it is noted that no where is it taught that CARBOPOL ™ is not a soluble adjuvant; and there is not teaching that depot adjuvants are not soluble adjuvants. Instead the Roberts and Lund references clearly polymer adjuvants, including CARBOPOL ™, are known to readily absorb water and due to its hydrophilic nature; therefore the adjuvant is soluble. The instant specification at page 15, lines 22-28, state that polymers, including liposomes are adjuvants that function by encapsulating the antigen and releasing them over a period of weeks to months. Roberts and Lund teach administering compositions using water dispersible, water soluble adjuvants, contrary to Appellants" statements.

Appellants' again argue that Roberts teaches against using an encapsulation polymer adjuvants that releases antigens slowly at the site of injection. A reference may be relied upon for all that it would have reasonably suggested to one having

ordinary skill the art, including nonpreferred embodiments. In the instant case, Roberts may be relied upon because it reasonably suggest to one having ordinary skill the art multicomponent vaccines comprising encapsulating adjuvants administered in a low dose volume of about 2 ml. Therefore, no more than routine skill would have been required to exchange the adjuvant of Roberts for the commercially available and functionally equivalent encapsulating polymer adjuvant of Lund since Lund teaches that adjuvant polymers are retained at the injection site for prolonged slow release of antigens.

Appellants' state that no mention is made for dosage ranges to be used with non-dispersible adjuvants, or any other types of adjuvants. And Appellants' assert that beyond the broad ranges mentioned, all specific examples provided by Roberts of such saponin, soluble adjuvant vaccine compositions were administered to cattle using 5 ml dosages (Example 3, pages 13-18).

Contrary to Appellants' arguments, Roberts should be relied upon because it reasonably suggest to one having ordinary skill in the art the administration of multicomponent vaccines in low dose volumes of about 2 ml or less. Roberts does not have to use each embodiment in an example to teach the effective dosage level. MPEP 2131.03 states that when the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, and the prior art discloses the claimed range with sufficient specificity, then the prior art anticipates the claims. Therefore, contrary to Appellants" statements about Roberts's broad teaching of low does volumes, Roberts clearly states with sufficient

specificity low dose multicomponent vaccines just as required by the instant claims. Therefore the disclosure of Roberts teaching a dosage of 1 to 5 ml and as low as 0.5ml would allow one of ordinary skill in the art to clearly envisage the instant claims range of about 2ml or less.

Furthermore, while Appellants' argue that Roberts does not teach examples comprising fewer than 5ml, however, Appellant is reminded that Appellants" own disclosure fails to show specific examples of a multicomponent clostridial vaccine comprising the non-clostridial *M .bovis* protective antigen wherein the vaccine is in a low dose volume of about 2 ml or less. Nor does Appellants" specification show examples of a multicomponent clostridial vaccine comprising non-clostridial *M. bovis* and *H. somnus* protective antigens wherein the vaccine is in a low dose volume of about 2 ml or less. Rather Appellants" specification merely mentions the possibility of having multicomponent clostridial vaccines combined with other antigens and mentions the possibility of having low dose volume vaccines. Therefore Appellants" arguments are not persuasive and the rejection should be maintained.

Response to Arguments Traversing the Rejection of Claims 46-48 Under 35 U.S.C. 112, first paragraph

Appellants' submit that the written description requirement has been met because Table 12 on page 54, the reduction in the number of lesions from the 5 ml dose when using the 2 ml dose is from 79.5% of the cattle to 46.3% of the cattle.

However it is Office's position that new matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter. In this case, Appellant has pointed to page 54 and Tables 12 and 13 of the instant specification and claims for support of the amendment. However the reduction of the incidence of lesions after weaning is only 33.2% not at least 41% in Table 12.

Appellants' believe that these results support a limitation as presently set forth in the claims that injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of the vaccine. The "at least" term finds support in Table14 on page 55, wherein the incident of lesions is reduced from 69.4% to 30.3%.

Contrary to Appellants' statements, Table 14 shows the quantity of trim in grams to remove injection site lesions after injection 5.0ml dose or 2.0ml doses of a 6-way clostridial vaccine. Here the 5.0ml dose caused a 69.4g lesion and the 2.0ml dose caused a 30.3g lesion. Therefore Appellants' statement "wherein the incident of lesions

is reduced from 69.4% to 30.3%" is a misstatement, since Table 14 shows the quantity of lesions removed, not percentage reduction. Thus, there appears to be no teaching of an injection site lesion formation being reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization. Therefore, it appears that the entire specification appears to fail to recite support for the method of immunizing cattle without significant injection site lesion formation comprising amount of injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six or seven clostridial organisms, a protective antigen component from *M. bovis* and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished. Thus, it appears that there is no support in the specification. Therefore, Appellants" arguments are not persuasive and the rejection should be maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/JaNa Hines/

Examiner, Art Unit 1645

Conferees:

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